REMARKS

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-6, 12-14, 16-18, 47, 48, 50-54 are pending in this application. Claims 15 and 49 are newly cancelled. Claim 1 is amended to incorporate the recitation of cancelled claim 15 and to write out the meaning of "EIAV." Claims 50 and 51 are amended to change their dependency. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claims are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

Information Disclosure Statement

The Examiner asserts that the September 27, 2006 Information Disclosure Statement (IDS) failed to comply with 37 CFR 1.98(a)(2). Enclosed is a copy of the return receipt postcard from the USPTO, indicating that copies of the IDS references were received with the September 27, 2006 submission. A copy of each listed reference is enclosed for the Examiner's convenience, along with a copy of the filed IDS. Applicants request that the Examiner consider and acknowledge consideration of the cited references, as the failure to do so was not due to Applicants' error.

II. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME

Claims 1-6, 12-18, 47, 48 and 50-54 were rejected under the second paragraph of Section 112 as allegedly being indefinite. The Examiner asserts that the abbreviation "EIAV" "can stand for various meanings." Office Action at 3. Although the meaning of EIAV it is quite clear from the specification, the full term has been spelled out in claim 1. Reconsideration and withdrawal of the indefiniteness rejection are requested.

Claims 1-6, 12-18, 47, 48 and 50-54 were rejected under the first paragraph of Section 112 as allegedly lacking enablement. The rejection is traversed.

In responding to the arguments made by Applicants in the September 27, 2006 Response, the Examiner states that Balaggan *et al.* (2006) and Balaggan *et al.* (2005) were not considered because the Examiner could not find the references. As discussed above with regard to the IDS, the return receipt postcard from the USPTO indicates that the cited references were received by the Office. Additional copies are enclosed for the Examiner's convenience.

The Office Action states: "Even if there is evidence for the therapeutic effect in treating retinal or choroidal neovascularization in the cited references, the method is only enabled for the particular vector and the administration routes used in the cited references." Office Action at 6. Regarding administration route, the claims specifically recite direct injection into the eye, which is the method used by Balaggan *et al.* in both studies.

Regarding the particular vector, as discussed in the September 27, 2006 Response, Example 4 of the specification teaches the construction of EIAV-based lentiviral vectors comprising polynucleotides encoding various angiostatic genes, such as endostatin and/or angiostatin, in operable linkage with physiologically regulated promoters, such as the HRE promoter, as well as constitutive promoters, such as the CMV promoter. In addition, the specification describes tissue-specific promoters for use in the claimed vectors.

By following the teachings of the specification, Applicants have demonstrated, in an art-recognized animal model of choroidal neovascularization (CNV), that delivery of EIAV-based lentiviral vectors carrying endostatin or angiostatin results in significant and comparable inhibition of both angiogenesis and vascular hyperpermeability. See Balaggan *et al.* (2006). Using the teachings of the specification, Applicants have also conducted a long term study demonstrating delivery of EIAV-based lentiviral vectors intraocularly. The study shows that these vectors produce efficient, long-term gene expression in different ocular tissues through different routes of intraocular delivery. See Balaggan *et al.* (2005).

With respect to the claimed antagonistic gene products, the claims are amended in accordance with the scope of enablement identified by the Examiner in prior Office Actions. Such amendments are made solely to advance prosecution and do not indicate Applicants' agreement with the Examiner's assessment. Applicants reserve the right to file continuing applications directed to the original claim scope.

Accordingly, reconsideration and withdrawal of the enablement rejection are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. At the very least, this paper raises no new issues for consideration and entry of this paper places the application in better condition for appeal.

Respectfully submitted,

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Serial No. 10/810,262 File No. 674523-2029.1 By TJK/Acy
Title in the Matter of the Application of POLYNUCLEOTIDE CONSTRUCTS et al
Applicant(s)/Inventor(s) Naylor et al.
The following due _____ in the U.S. Patent Office was received in the Patent Office

- ☐ Affidavit
- ☐ Declaration
- ☒ Amendment + Response to Office Action
- ☐ Preliminary Amendment
- ☐ Amendment After Final Rejection
- ☐ Request for Extension of Time
- ☐ Provisional Patent Application
- ☐ Application for Patent, including ____ Pages Specification ____ Claims ____ Abstract
- ☐ Declaration ☐ Oath ☐ Power
- ☐ Request for Filing Continuation or Divisional Application _____ sheets
- ☐ PCT Request _____ sheets, including
- ☐ Transmittal Letter
- ☐ Request for Continued Exam (RCE)
- ☐ Assignment ☐ Recordation Cover Sheet
- ☐ Amendment Fee Transmittal
- ☐ Claim of Priority
- ☐ Request for Approval of Drawings
- ☐ Diskette with Sequence Listing
- ☒ Express Mail Mailing Label # EV468994045US
- ☐ (separate sheet)
- ☒ Check No. 041534 for $180.00
- ☐ Amex Payment No. _____ for $ _____
- ☐ Deposit Account Order Form
- ☐ Drawing _____ Sheet(s)
- ☒ Information Disclosure Statement (Supplemental)
- ☒ PTO Form 1449
- ☐ Issue Fee/Publication Fee Transmittal
- ☐ Appeal Brief (triplicate) ☐ Letter
- ☐ Application for TM Registration including _____ Specimens
- ☐ Status Request ☐ Notice of Appeal (triplicate)
- ☐ Petition ☐ Response
- ☐ Priority Document ☐ Statement of Use
- ☐ Response to Examiner's Statement
- ☐ Search Report
- ☐ Response to Notice to File Missing Parts
- ☒ Cited References for IDS + Amendment.